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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 7,214,364 was filed on March 31, 2010, under 35 U.S.C. § 156. Please note that Applicant has also applied for extension for U.S. Patent Nos. 7,427,633 and 7,208,141 for NDA No. 50-814 pursuant to the provisions of 37 C.F.R. § 1.785.

The assistance of your Office is requested in confirming that the product identified in the application, CAYSTON® (aztreonam), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

If the Food and Drug Administration (FDA) required regulatory review of NDA 50-814 as directed to a drug product containing aztreonam as the sole active ingredient, then USPTO's review of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. § 156 as failing to comply with section 156(a)(5)(A) since aztreonam was previously approved in the drug product AZACTAM® in 1986.

FDA is requested to indicate which of the following statements is correct: (i) the active ingredient in CAYSTON® is aztreonam, as indicated in the electronic records of the FDA (see attached); or (ii) the active ingredient in CAYSTON® is aztreonam with lysine, as asserted by Applicant.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Frank P. Grassler
Vice President Intellectual Property
Gilead Sciences, Inc.
333 Lakeside Dr.
Foster City, CA 94404

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Drug Details

Drug Name(s)	**CAYSTON (Brand Name Drug)**
FDA Application No.	**(NDA) 050814**
Active Ingredient(s)	**AZTREONAM**
Company	**GILEAD**
Original Approval or Tentative Approval Date	**February 22, 2010**
Chemical Type	**3 New formulation**
Review Classification	**S Standard review drug**

- **There are no Therapeutic Equivalents**
- **Label Information**
- **Approval History, Letters, Reviews, and Related Documents**

Products on Application (NDA) #050814
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
CAYSTON	AZTREONAM	75MG/VIAL	FOR SOLUTION; INHALATION	Prescription	Yes	None

Back to Top | Back to Previous Page | Back to Drugs@FDA Home

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